510(k) Summary

NOV 1 5 2001

K013608

Date:	September 20, 2001
Submitter's Name:	Toshiba America Medical Systems, Inc.
Submitter's Address:	P.O. Box 2068, 2441 Michelle Drive, Tustin, CA 92781-2068
Submitter's Contact:	Diana Thorson, Senior Regulatory Affairs Specialist, (714) 730-5000, Extension 4121
Device Proprietary Name:	Digital Radiography System, Model DFP-8000D
Classification Name:	Image Intensified Fluoroscopic X-Ray System (Accessory)
Common Name:	Image Processor [Fed. Reg. No. 892.1650, Product Code: JAA]
Predicate Device:	Toshiba DFP-2000A/A4 (K941611)

Description of this Device:

The Digital Radiography System, Model DFP-8000D is a Digital Radiography Processor used in diagnostic X-ray angiography systems. This system processes, displays, and records digital images obtained from the detectors of X-ray TV systems (such as CCD cameras), and replays the recorded images.

Summary of Intended Uses:

The Digital Radiography System, Model DFP-8000D is a Digital Radiography Processor used in diagnostic X-ray angiography systems. This system processes, displays, and records digital images obtained from the detectors of X-ray TV systems (such as CCD cameras), and replays the recorded images for image diagnosis. This system is intended for use in diagnostic and interventional procedures for cardiac blood vessels, cerebral blood vessels, abdominal blood vessels, and lower limb blood vessels. This device employs no intended uses that are not in cleared devices already found in the marketplace.

Technological Characteristics:

The technological characteristics of this device are the similar to that of the predicate device. The differences in technological characteristics are due to the employment of updated technologies such as updated image processing, image memory, operating system, and CPU.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Toshiba America Medical Systems, Inc.
% Mr. Mark Job
TUV Product Service
1775 Old Highway 8 NW, Suite 104
NEW BRIFHTON MN 55112-1891

MAY - 7 2012

Re: K013608
Trade/Device Name: Digital Radiography System; Model DFP-8000D
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB and JAA
Dated: October 30, 2001
Received: October 31, 2001

Dear Mr. Job:

This letter corrects our substantially equivalent letter of November 15, 2001.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

NOV 1 5 2001

510 (k) Number (If Known): K013608

Device Name: Toshiba Digital Radiography System, Model DFP-8000D

Indications For Use:

The Digital Radiography System, Model DFP-8000D is a Digital Radiography Processor used in diagnostic X-ray angiography systems. This system processes, displays, and records digital images obtained from the detectors of X-ray TV systems (such as CCD cameras), and replays the recorded images for image diagnosis. This system is intended for use in diagnostic and interventional procedures for cardiac blood vessels, cerebral blood vessels, abdominal blood vessels, and lower limb blood vessels.

(Please do not write below this line - Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-the-Counter Use _____

(Optional Format 1-2-96)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

510 (k) Number: K013608